



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,842	09/09/1999	SAMUEL P. SAWAN	SUR-008	1863

7278 7590 11/18/2003

DARBY & DARBY P.C.
P. O. BOX 5257
NEW YORK, NY 10150-5257

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 11/18/2003

30

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/392,842

Applicant(s)

SAWAN ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58,60-71 and 89-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58,60-71 and 89-100 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28, 29.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1617

DETAILED ACTION

Amendment filed on July 28, 2003 has been entered. Claims 58, 60-71, 89-100 are pending.

Prosecution on the elected bigunide polymer specie of poly(hexamethylenebiguanide), and water-insoluble organic compound specie of methylene-bis-N,N-diglycidylaniline, as set forth in Paper No. 8, is hereby continued.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments and the arguments.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 58, 60-64, 89-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown US Patent 4,643,181.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that Applicants' film is moisture-resistant. In response, Examiner states that the limitation "wherein the composition forms a moisture-resistant film on the skin" is a functional property of the composition used in the instantly claimed methodology. Brown teaches compositions that meet all elements of the instant composition, therefore, Brown's composition inherently is capable of providing the same functional characteristic as the instantly employed composition; namely, forming a

Art Unit: 1617

moisture-resistant film. The instant claims are directed to methods of using a composition comprising administering to a skin a composition comprising a biguanide polymer and a carrier. Brown provides for the instant elements of the composition.

Brown also provides for direct administration of his composition to skin. Applicant has not provided any evidence showing the contrary. Therefore, Brown meets all elements of the claimed methods.

Applicant also argues that the composition of Brown is soluble in water. In response, Examiner states that the instant compositions do not exclude the elements of Brown's compositions because the claims employ the transitional phrase "comprising."

Claims 58, 60-71, 89-100 are rejected under 35 U.S.C. 102(e) as being anticipated by Sawan et al US Patent 5,817,325.

Applicant's arguments with respect to this rejection have been considered but are not persuasive. Applicant argues that nothing is taught or suggested to imply that powder dispersion of Swan would form a film on the wound or skin.

Similar to the arguments presented above, Examiner replies that if the elements of the instantly employed compositions is taught in the prior art, the functional characteristics of them are also provided. Here, Sawan's compositions meet all elements of the instant composition. Sawan teaches application on the wound or skin, therefore, his composition is inherently capable of forming the film that is instantly claimed. Moreover, Examiner points out that the instantly claimed method employ a carrier that is in powder form. Sawan in '325 also teaches a powder form formulation.

Art Unit: 1617

Therefore, the instantly employed compositions encompass the prior art compositions and their functional characteristics.

Claims 58, 60, 68-71, 90-100 are rejected under 35 U.S.C. 102(b) as being anticipated by Larkin et al, Ophthalmology 1992: 99: 185-191.

Larkin teaches topical administration of PHMB for treating infection in six patients (see abstract, and pages 186-190). Since Lakin's PHMB polymer contains all elements of the instant polymer, it is also capable of forming covalent bonding. Accordingly, Larkin meets the limitations of the instant claims.

Double Patenting

Claims 58, 60-71, 89-100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-38 of U.S. Patent No. US 6,180,584, claims 1-6 US Patent 6,030,632, claims 1-9, US Patent 5,869,072, claims 1-9, US Patent 5,817,325.

Examiner noted Applicant statement indicating that an appropriate terminal disclaimer will be filed once allowable subject matter is determined.

Claim Rejections - 35 USC § 103

Claims 58, 60-71, 89-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown US Patent 4,643,181 in view of Sawan et al WO 95/17152 ('152).

Applicant argues that cross-linking the PHMB component of Brown will destroy it's intended function. However, applicant provides no evidence supporting this conclusion.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In the instant case, the cited prior art teach all elements of the instant claims. Sawan '152 also provides ample expectation of success. Therefore, the combined teachings of the references render the instant claims obvious.

Claims 58, 60-71, 89-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowry et al US Patent 6,509,022.

Lowry teaches polymeric bigunaide compositions for topical delivery. Lowry's compsoiton contains all elements of the instant composition. (col 4-6). Lowry does not specifically administer his compositions to the skin.

However, since Lowry's compositions are taught as cosmetic composition for personal care, it would have been obvious to one of ordinary skill in the art at the time of invention to apply Lowry's compositions directly to skin because Lowry suggests such an intended use.

Conclusion

No claims are allowed.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 10/06/2003 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS**

Art Unit: 1617

MADE FINAL. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.


RUSSELL TRAVERS
PRIMARY EXAMINER